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PATENT TRADEMARK OFFICE

Docket No.: 6485/16895

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: GIANCARLO SANTUS, GIUSEPPE BOTTONI, ETTORE BILATO

Serial No.: Not Yet Assigned Art Unit: Not Yet Assigned

Filed: concurrently herewith Examiner: Not Yet Assigned

For: **THERAPEUTIC COMPOSITIONS FOR INTRANASAL
ADMINISTRATION WHICH INCLUDE KETOROLAC**

Continuation of U.S. Application Serial No.08/383,707 Filed: February 1, 1995

PRELIMINARY AMENDMENT

Honorable Commissioner for
Patents and Trademarks
Washington, D.C. 20231

Before examination, kindly amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the claims pursuant to 37 C.F.R. §1.121 as follows:

Please add new claims 19-25 as follows:

19. (New) A pharmaceutical nasal spray comprising an effective amount of a ketorolac-based analgesic admixed with a phospholipid or a bioadhesive polymer, said spray when administered intranasally having a therapeutic blood level compared to that of the same spray when injected.

20. (New) The pharmaceutical nasal spray of claim 19 wherein the ketorolac-based analgesic is ketorolac tromethamine.

21. (New) The pharmaceutical nasal spray of claim 19 wherein the analgesic is present in the composition in an amount of between 5 to 20% by weight based on total weight of the composition.

22. (New) The pharmaceutical nasal spray of claim 21 wherein the analgesic is present in the composition in an amount of 15% by weight based on total weight of the composition.

23. (New) The pharmaceutical nasal spray of claim 19 wherein the bioadhesive polymer is selected from the group consisting of polyacrylics, cellulosics, and gums.

24. (New) The pharmaceutical nasal spray of claim 19, said spray being free of absorption enhancers.

25. (New) A pharmaceutical nasal spray consisting of an effective amount of a ketorolac-based analgesic admixed with a bioadhesive polymer, said spray when administered intranasally having a therapeutic blood level compared to that of the same spray when injected.

REMARKS

Consideration of this amendment and of the application is respectfully requested.

New claims 19-25 have been added. No new subject matter has been added as a result of the present amendment. The newly added claims 19-25 find support in the original claims and throughout the original specification. Specific support can be found, for example, in the following parts of the application:

1. "a pharmaceutical nasal spray comprising an effective amount of ketorolac" - p. 4, ll. 23-24; p. 6, ll. 1-3; p. 6, l. 34 - p. 7, l. 7; original claims 1 and 12 (*see parent application Serial No. 07/875,700*);
2. "ketorolac-based analgesic" - p. 1, ll. 14-34; p. 3, ll. 15-27; original claims 12 and 17 (*see parent application Serial No. 07/875,700*);
3. "ketorolac-based analgesic admixed with a phospholipid" - p. 6, ll. 20-28; original claims 10-11 (*see parent application Serial No. 07/875,700*);
4. "ketorolac-based analgesic admixed with a bioadhesive polymer selected from the group consisting of polyacrylics, cellulosics, and gums" - p. 5, ll. 17-31 (polyacrylics [also p. 7, ll. 8-20; Example 4], cellulosics [also p. 7, ll. 8-20; Examples 3, 6], gums, alginates, agar-agar); original claim 8 (*see parent application Serial No. 07/875,700*);
5. "said spray when administered intranasally having a therapeutic blood level compared to that of the same spray when injected" - p. 18, l. 17 - p. 19, l. 5 (Table 8); original claim 18 (*see parent application Serial No. 07/875,700*);

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6. "ketorolac tromethamine" - p. 6, ll. 17-18; Examples 1-9 and 13-15;
7. a pharmaceutical nasal spray "free of absorption enhancers" and containing (i) an effective amount of ketorolac-based analgesic dissolved in water or buffer; and (ii) a bioadhesive polymer - Examples 3 and 6;
8. "the analgesic is present in the composition in an amount of between 5 to 20% by weight based on total weight of the composition" - p. 4, ll. 19-21; Examples 1-9 (5%); Examples 13-15 (15%); original claims 4, 7 and 15-16 (*see parent application Serial No. 07/875,700*);
9. "the analgesic is present in the composition in an amount of 15% by weight based on total weight of the composition" - p. 4, ll. 19-21; Examples 13-15; original claims 7 and 16 (*see parent application Serial No. 07/875,700*);
10. "a pharmaceutical nasal spray consisting of an effective amount of a ketorolac-based analgesic admixed with a bioadhesive polymer" – p. 5, ll. 17-31; p. 6, ll. 28-30; original claim 8 (*see parent application Serial No. 07/875,700*), and Example 3.

Applicants respectfully note that new claims 19-25 of this application correspond substantially to claims of U.S. Patent No. 6,090,368 to Zia *et al.* issued on July 18, 2000 ("‘368 patent", copy attached as part of the accompanying Information Disclosure Statement)¹. Specifically, new claims 19, 24, and 25 correspond substantially to the independent claim 1 of the ‘368 patent; claim 20 corresponds substantially to the dependent claim 2 of the ‘368 patent; claims 21 and 22 correspond substantially to the dependent claim 3 of the ‘368 patent; claim 23 corresponds substantially to the dependent claim 4 of the ‘368 patent. New claims 19-25 are presented in compliance with 35 U.S.C. §135(b) as being "for the same or substantially the same

¹ This information is provided in compliance with MPEP 2307.05.

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subject matter as a claim of an issued patent" and "made prior to one year from the date on which the patent was granted" (*i.e.*, prior to July 18, 2001).

CONCLUSION

Applicants request entry of the foregoing amendments and remarks in the file history of this application. In view of the above remarks, it is respectfully submitted that claims 1-25 in the present application are free from any ground for rejection. An early determination of allowability is respectfully requested.

Respectfully submitted,

Dated: July 12, 2001



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